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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/470,735	06/06/95	ISRAELI	R 41426-D/JFW/
			EXAMINER

HM22/0831

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CLASSIFICATION	PAPER NUMBER
1645	20

DATE MAILED:
08/31/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 6/17/99
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 94-96, 98-101, 105-113 is/are pending in the application.
- ☐ Of the above, claim(s) 107-112 is/are withdrawn from consideration.
- ☒ Claim(s) 94-96, 99-101 is/are allowed.
- ☒ Claim(s) 98, 105-106, 113 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 107-112 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e)

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s) (PTO-1449) (Paper No(s)) _____
- ☒ Interview Summary, PTO-413
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☒ Notice of Informal Patent Application, PTO-152

SEE OFFICE ACTION ON THE FOLLOWING PAGES-

Part III DETAILED ACTION

Response to Amendment

1. Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.129(a). Applicant's first submission after final filed on 6/17/99 has been entered.
2. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Applicant should be aware that 104 claims were of record before the instant amendment. Therefore, according to Rule 126, the newly submitted claims 102-110 have been renumbered as 105-113 and their dependencies have been changed accordingly.
5. Newly submitted claims 107-112 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 107-109 are drawn to original Group IX, claims 37-39, drawn to a therapeutic agent comprising said antibody and cytotoxic agent, classified in class 424, subclass 138.1. Claims 110-112 are drawn to original Group X, claims 39-45, drawn to a method of detection using said antibody and composition comprising said antibody and carrier (or radioisotope), classified in class 435, subclass 7.1.

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Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 107-112 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

6. The allowability of claim 98 was indicated in error and is withdrawn as claim 98 was dependent on a rejected and canceled claim. The Examiner regrets this error.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 98 and 105-106 are rejected under 35 U.S.C. 102(b) as anticipated by Feng et al. 1991. Feng et al discloses of an isolated PSM antigen with a molecular weight of 100 kda and a monoclonal antibody which reacts with said antigen.

Applicant's arguments filed 6/17/99 have been fully considered but they are not persuasive. Applicant argues that the declarations of Kaladas, Rodwell, and Horoszewicz establish that the Feng reference is not enabling due to the lack of public availability of the 7E11-C5 hybridoma cell line. However, the 102(b) statute above clearly states that if the invention was described in a printed publication or in public use, the statute would apply. It is not required that the invention be described and be in public use. Regarding Applicant's arguments that the disclosure of the specific 7E11-C5 antibody should not anticipate a genus claim, since the Patent Office does not

have the facilities for examining and comparing applicants' proteins with the proteins of the prior art reference, the burden is upon applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed proteins and the proteins of the prior art.

See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

9. Claim 113 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as originally filed provides no support for the concept of a genus of antibody which binds to prostate specific membrane antigen other than the known 7E11-C5 monoclonal antibody. Any negative limitation or exclusionary proviso must have basis in the original disclosure. See *Ex parte Graselli*, 231 USPQ 393 (Bd. Pat. App. 1983) *aff'd mem.*, 738F.2d 453 (Fed Cir. 1984).

10. Claims 94-96 and 99-101 are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Thursday from 0730 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached on (703) 308-3995. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Stephen Gucker

August 30, 1999



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